K090629

510(k) SUMMARY

1. DATE PREPARED

February 20, 2009

2. SPONSOR INFORMATION JUN - 4 2009

Address

TYSON BIORESEARCH, INC.
5 F., # 22, KE E. ROAD III., SCIENCE BASED INDUSTRIAL PARK
CHUN-NAN, MIAO-LI COUNTY, CHINA (TAIWAN) 350

Contact Person: WEN-HAI TSAI

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3. NAME OF DEVICE:

Trade Name:	Easy Step Blood Glucose Monitoring System DIACHEX+ PRO Blood Glucose Monitoring System
Common Names/Descriptions:	Blood Glucose Monitoring System
Classification Names:	Glucose test system, product code 75CGA and "System, test, blood glucose, over the counter", product code 75NBW, 21 CFR 862.1345

4. DEVICE DESCRIPTION:

The Easy Step / DIACHEX+ PRO Blood Glucose Monitoring System designed by Tyson Bioresearch Inc., an amperometric biosensor, is adopted for its ease of use, its ability to process accurate results utilizing only a small volume of blood, and its quick response time. Easy Step / DIACHEX+ PRO provide a convenient and safe monitoring system for diabetes health care professionals, hospitals and most importantly, people with diabetes.

The Easy Step / DIACHEX+ PRO Blood Glucose Monitoring System is intended for use in the quantitatively measurement of glucose (sugar) in fresh capillary whole blood from the fingertip and the alternative sites: the palm and the forearm. The Easy Step / DIACHEX+ PRO Blood Glucose Test Strips are for testing outside the

body (in vitro diagnostic use). When the edge of the test strip is touched to a drop of blood, the test strip draws the blood into the sample chamber and the glucose reading is displayed on the meter after 5 seconds. The test measures glucose from 20 mg/dL (1.1mmol/L) to 600 mg/dL (33.3 mmol/L). The test strip is calibrated to display the equivalent of plasma glucose values to allow the comparison of results with laboratory methods.

5. INTENDED USE:

The Easy Step / DIACHEX® PRO Blood Glucose Monitoring System is intended for use in the quantitatively measurement of glucose (sugar) in fresh capillary whole blood from the fingertip and the alternative sites: the palm and the forearm. The Easy Step / DIACHEX® PRO Blood Glucose Test Strips are for testing outside the body (in vitro diagnostic use). The Easy Step / DIACHEX® PRO Blood Glucose Monitoring System is intended for use at home (over the counter [OTC]) by persons with diabetes, or in clinical setting by healthcare professionals as an aid in monitoring the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus. The alternative site testing in the systems can be used only during steady-state blood glucose conditions. It is not intended for neonatal testing.

6. TEST PRINCIPLE

The test principle is based on electrochemical biosensor technology using glucose oxidase. Glucose is oxidized to gluconic acid and electrons are produced from the reaction. The electrons are then trapped by a chemical mediator, potassium ferricyanide. Once the enzymatic reaction is complete, a potential is provided by the meter for a further electrochemical reaction in order to generate a current from the release of trapped electrons. This current is then measured and correlated to the glucose concentration in the whole-blood sample. The test strip is calibrated to display the equivalent of plasma glucose values to allow easy comparison of results with laboratory methods.

7. PREDICATE DEVICE:

Predicate device name(s): DIACHEX® INFINITY Blood Glucose Monitoring System

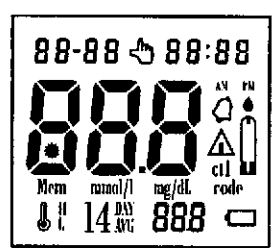
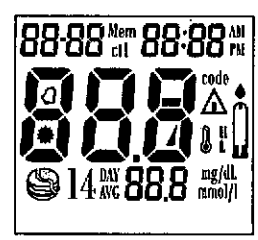
Predicate 510(k) number(s): k073492

Comparison with predicate:

This 510(K) amendment addresses the changes of the DIACHEX® INFINITY Blood

Glucose Monitoring System (k073492). The modifications encompass the change for operating process, addition of selectable backlight on/off function, addition of graphic indicator for pre-meal and post-meal test results on the LCD result display of Easy Step / DIACHEX+ PRO meter and the removal of hypoglycemic and hyperglycemic alarm setting function and the change for meter outside looking of Easy Step Glucose meter only. All the main internal electronic component, function and detection algorithm of proposed devices remain the same as DIACHEX+ INFINITY Blood Glucose Meter. The chemical formula and used enzyme of the Easy Step / DIACHEX+ PRO test strip is identical to the original cleared device test strip (K062829) without ant change. The table below lists the differences between the Easy Step and DIACHEX+ PRO device from the predicate DIACHEX+ INFINITY device.

Differences:

Item	Predicate Device (K073492)	Proposed Device	
	DIACHEX+ INFINITY	Easy Step	DIACHEX+ PRO
Hypoglycemic and hyperglycemic alarm	2 user setting alarms	none	2 user setting alarms
Backlight	none	Selectable backlight on/off by user	
LCD Display		Increase pre/pro meal test result indicator 	
Coding	Fixed code	Fixed code	Glucode chip
PC link mode	Enter PC link mode by setting meter	Automatically enter PC link mode when plugging in the USB cable	
Memory mode	Press M button to read average and 300 test result memories	Press M button to read 300 test result memories, press S button to read average results	
Meter Appearance			
Meter Size	92 x 58 x 19 (mm)	79 x 60 x 17 (mm)	92 x 58 x 19 (mm)
Meter Weight	Appx. 60 grams	Appx. 55 grams	Appx. 60 grams

8. PERFORMANCE CHARACTERISTIC SUMMARY

Within day precision test was performed with 5 levels of spiked whole blood each with one lot test strip. Samples were tested with 100 measurements obtained from 10 meters with each level of blood sample. Results are summarized below.

Unit:mg/dL		YSI	AVG	Bias %	Std	CV %
Proposed Device	Easy Step	43.8	42.6	-2.8	2.47	5.80
		87.8	85.1	-3.1	2.92	3.43
		132	135.7	2.8	4.65	3.42
		206	209.2	1.5	4.98	2.38
		320	323.4	1.0	6.72	2.08
	DIACHEX+ PRO	45.6	45.3	-0.6	2.30	5.08
		82.1	83.8	2.1	3.04	3.62
		126	124.5	-1.2	3.76	3.02
		224	219.4	-2.0	5.63	2.56
		337	334.3	-0.8	7.25	2.17
Predicate Device	DIACHEX+ INFINITY	39.7	40.7	2.6	2.22	5.45
		92.4	89.3	-3.4	2.45	2.74
		136	139.2	2.4	4.50	3.23
		243	240.0	-1.2	5.49	2.29
		354	349.0	-1.4	7.09	2.03

Linearity test was performed with 10 levels of spiked whole blood. Samples were tested with 10 measurements obtained from 10 meters with each level of blood sample using one lot test strip. The linear response range of proposed meter was defined from 20 to 600 mg/dL and the actual studies were performed from ~25 to ~566 mg/dL. Linear regression results compared to YSI are summarized below.

Device	Proposed Device		Predicate Device
	Easy Step	DIACHEX+ PRO	DIACHEX+ INFINITY
Slope	1.01	1.00	1.01
Intercept	-1.11	0.41	-0.23
R2	0.9997	0.9996	0.9998
sy.x	5.45	6.66	6.77

To ensure that Easy Step, DIACHEX+ PRO and DIACHEX+ INFINITY system

similarly, clinical accuracy was assessed in an in-house study performing by technician.129 participants both males and females ranged from age with sample ranged from 33.2 to 577mg/dL and hematocrit ranged from 34% to 53%. Values obtained from meters were compared to YSI results; linear results regression analysis yielded the following results:

Fingertip	Proposed Devices		Predicate Device
	Easy Step	DIACHEX+ PRO	DIACHEX+ INFINITY
N	129	129	129
Slope	1.03	1.01	1.02
Intercept	2.18	3.10	1.44
R2	0.9887	0.9890	0.9871

The alternate site testing was also been evaluated.

Easy Step	Finger vs YSI	Palm vs YSI	Palm vs Finger	Forearm vs YSI	Forearm vs Finger
N	113	113	113	113	113
Slope	1.03	1.01	0.98	1.01	0.97
Intercept	2.99	3.06	1.92	0.81	0.43
R2	0.9797	0.9767	0.9871	0.9734	0.9753

DIACHEX+ PRO	Finger vs YSI	Palm vs YSI	Palm vs Finger	Forearm vs YSI	Forearm vs Finger
N	113	113	113	113	113
Slope	1.02	1.01	0.99	1.03	1.00
Intercept	4.92	3.02	0.58	-2.72	-3.97
R2	0.9815	0.9769	0.9856	0.9705	0.9659

DIACHEX+ INFINITY	Finger vs YSI	Palm vs YSI	Palm vs Finger	Forearm vs YSI	Forearm vs Finger
N	113	113	113	113	113
Slope	1.02	1.02	0.98	1.02	0.99
Intercept	2.53	-0.40	-0.45	-1.08	-1.42
R2	0.9770	0.9763	0.9739	0.9759	0.9766

The acceptable criteria is the ISO 15197 requirement of 95% of individual glucose results falling within ±15mg/dL at glucose concentration for samples <75mg/dL and within ±20% at glucose concentrations≧75mg/dL. The samples that met the ISO 15197 requirement were summarized in the table below.

Device	Proposed device		Predicate device
Sample Site	Easy Step	DIACHEX+ PRO	DIACHEX+ INFINITY
Finger	98.4%	99.2%	100%
	(127 / 129)	(128 / 129)	(129 / 129)
Palm	100.0%	98.2%	98.2%
	(113 / 113)	(111 / 113)	(111 / 113)
Forearm	98.2%	96.5%	97.3%
	(111 / 113)	(109 / 113)	(110 / 113)

From the above test results, we conclude that the modification of the DIACHEX+ INFINITY Meter do not affect the effectiveness and safety of the device. The proposed device Easy Step / DIACHEX+ PRO Blood Glucose Monitoring System is substantial equivalent to the original cleared device. The performance characteristics of the proposed system under various conditions including temperature effect, altitude effect, hematocrit levels, interference study, sensitivity and linearity has been established in the previously device cleared under k073492. Easy Step / DIACHEX+ PRO system are suitable for its intended use. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JUN - 4 2009

Re: k090629
Trade/Device Name: Easy Step/DIACHEX^{+} PRO Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: May 4, 2009
Received: May 5, 2009

Dear Dr. Tsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K090629

Device Name: Easy Step / DIACHEX$^+$ PRO Blood Glucose Monitoring System

Indication for Use:

The Easy Step / DIACHEX$^+$ PRO Blood Glucose Monitoring System is intended for use in the quantitatively measurement of glucose (sugar) in fresh capillary whole blood from the fingertip and the alternative sites: the palm and the forearm. The Easy Step / DIACHEX$^+$ PRO Blood Glucose Test Strips are for testing outside the body (in vitro diagnostic use). The Easy Step / DIACHEX$^+$ PRO Blood Glucose Monitoring System is intended for use at home (over the counter [OTC]) by persons with diabetes, or in clinical setting by healthcare professionals as an aid in monitoring the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus. The alternative site testing in the systems can be used only during steady-state blood glucose conditions. It is not intended for neonatal testing.

Prescription Use X	And/Or Over the Counter Use X
(21 CFR Part 801 Subpart D)	(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K090629